## UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CITY OF HUNTINGTON, Plaintiff,

v. AMERISOURCE BERGEN DRUG CORPORATION, et al.,

Defendants.

Civil Action No. 3:17-cv-01362

CABELL COUNTY COMMISSION, Plaintiff,

v.
AMERISOURCE BERGEN DRUG
CORPORATION, et al.,
Defendants.

Consolidated case: Civil Action No. 3:17-cv-01665

PLAINTIFFS' MEMORANDUM IN SUPPORT OF MOTION FOR PARTIAL SUMMARY JUDGMENT REGARDING TRANSACTIONS REFLECTED IN PROCESSED ARCOS DATA

# TABLE OF CONTENTS

	Page
TABLE OF AUTHORITIES	. iii
INTRODUCTION	.1
STATEMENT OF FACTS	.2
ARGUMENT	.6
CONCLUSION	.8

# TABLE OF AUTHORITIES

Cases:	Page(s)
Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 256 (1986)	7
Dash v. Mayweather, 731 F.3d 303, 311 (4th Cir. 2013)	8
Gill v. Rollins Protective Servs. Co., 7 73 F.2d 592, 595 (4th Cir.1985)	7
In re Bos. Sci. Corp., Pelvic Repair Sys. Prod. Liab. Litig., No. 2:12-CV-00904, 2015 WL 1527678 (S.D. W.Va. Apr. 2, 2015)	7
Pettengill v. United States, 867 F.Supp. 380, 381 (E.D.Va.1994)	7
Stone v. Liberty Mut. Ins. Co., 105 F.3d 188, 191 (4th Cir. 1997)	8
Constitutional Provisions, Statutes and Rules:	
Federal Rule of Civil Procedure 56	

Plaintiffs, pursuant to Rule 56 of the Federal Rules of Civil Procedure, seek an order granting partial summary judgment and holding that the Automation of Reports and Consolidated Orders System ("ARCOS") electronic data, received from the Drug Enforcement Administration ("DEA") ("ARCOS Data") and processed by Plaintiffs' expert Dr. Craig J. McCann accurately reflects the shipments of opioid products reported to the DEA by DEA licensed wholesale distributors ("Processed ARCOS Data"). Because Defendants have not challenged Dr. McCann's processing of the ARCOS Data, and many of their experts have instead relied upon the Processed ARCOS data, no genuine issue of material fact exists on this point. Plaintiffs now file this memorandum in support of this motion, the granting of which would significantly streamline the trial.

#### INTRODUCTION

The ARCOS Data provides information regarding the pills shipped by manufacturers and distributors into the plaintiff jurisdictions and as such it is a critical piece of evidence in the litigation. However, the raw data as originally provided by the DEA was not in usable form. To render it usable, plaintiffs' expert Dr. Craig McCann processed it as described below. While the defendants have challenged a number of Dr. McCann's opinions, they have not challenged, here or anywhere else in the litigation, Dr. McCann's processing of the ARCOS data.

<sup>&</sup>lt;sup>1</sup> A hard drive containing the ARCOS Data and Processed ARCOS Data has been separately filed with the Clerk as an Appendix to Plaintiffs' Motion. (Ex. 1).

Thus far, the Processed ARCOS data has been used in both state and federal courts across the country. These Defendants have cross-examined Dr. McCann five times regarding his processing of the ARCOS Data. At no time have they argued Dr. McCann's processing of the data was improper in any way, nor have they argued that the Processed ARCOS Data does not accurately reflect the information provided to the parties by the DEA either through expert testimony or otherwise. Indeed, their own experts rely on this same Processed ARCOS data. Because there is no disputed issue of fact, this Court should grant partial summary judgment and hold that the Processed ARCOS Data accurately reflects the reports DEA licensed distributors made to the DEA regarding their shipments of opioids.

### STATEMENT OF FACTS

ARCOS is the system through which manufacturers and distributors report every transaction of controlled substances to the DEA.<sup>2</sup> In the MDL, the DEA produced a set of ARCOS Data reflecting transactions of drug products containing one or more of fourteen opioid drugs during the time period January 1, 2006 through December 31, 2014.<sup>3</sup> In total, this ARCOS Data contains 500,709,803 transaction records.<sup>4</sup> In the MDL, the Defendants stipulated to the accuracy of the ARCOS Data

<sup>&</sup>lt;sup>2</sup> See August 3, 2020 Expert Report of Craig J. McCann, Ph.D., CFA (Ex. 2 at 10).

<sup>&</sup>lt;sup>3</sup> *Id.* The fourteen drugs are listed in footnote 5 below.

<sup>&</sup>lt;sup>4</sup> *Id.* at 11.

as produced by the DEA.<sup>5</sup> The ARCOS Data in its raw form, however, could not readily be understood or analyzed without first being processed.

The ARCOS Data was produced by the DEA and stored on a local server at Dr. McCann's office.<sup>6</sup> Dr. McCann input the raw data into a statistical software program, correcting errors in a small number of records.<sup>7</sup> As produced by the DEA, the ARCOS Data has 34 fields for each transaction record.<sup>8</sup> Dr. McCann added several fields to the ARCOS Data to assist in his analysis.<sup>9</sup> Dr. McCann also removed seven types of transactions from the ARCOS Data before conducting further analysis.<sup>10</sup> None of Dr.

<sup>&</sup>lt;sup>8</sup> ARCOS Data Fields Produced by DEA (Ex. 2, Figure 1, p. 12):

	1.7	Rep	ort	cr/	Sell	ler l	afo	× .	100	Buyer Info										Transaction Info													
DEA #	Business Activity	Name	Addl Co Info	Address1	Address2	City	State	Zip	County	DEA#	Business Activity	Name	Addi Co Info	Address1	Address2	City	State	Zφ	County	Transaction Code	Drug Code	NDC Number	Drug Name	Quantity	Unit	Action Indicdator	Order Form Number	Correction Number	Strength	Transaction Date	Calc Base Weight Grams	Dosage Unit	a protection and

<sup>&</sup>lt;sup>9</sup> The fields added were as follows: drug labeler names from the FDA, drug labeler company families, seller company families, drug product potency information from the CDC's Morphine Milligram Equivalents (MME) conversion table, and buyer business activities from the Centers for Medicare and Medicaid Services. (Ex. 2 at 21).

2042642.1 4

<sup>&</sup>lt;sup>5</sup> Parties' Joint Stipulation, Doc. 2675 at p. 2, ¶ 16. ("The documents produced by the United States Drug Enforcement Administration ("DEA") related to the Automated Records and Consolidated Orders System ("ARCOS Data") reflecting transactions in drug products containing one or more of fourteen drugs: buprenorphine, codeine, dihydrocodeine, fentanyl, hydrocodone, hydromorphone, levorphanol, meperidine, methadone, morphine, powdered opium, oxycodone, oxymorphone, and tapentadol for the period of January 1, 2006 through December 31, 2014 shall be deemed authentic and presumed admissible for the purposes of this litigation.").

<sup>&</sup>lt;sup>6</sup> See September 1, 2020 Deposition of Dr. McCann (Ex. 3 at 151).

<sup>&</sup>lt;sup>7</sup> *Id.* at 153.

<sup>&</sup>lt;sup>10</sup> Dr. McCann removed the following: (1) Obvious duplicate transactions, when the same transaction was reported to ARCOS more than once by the same registrant; (2) transactions where the Drug Code from the NDC Dictionary is not one of the 14

McCann's changes altered the substance of the ARCOS data provided by the DEA.

The resulting Processed ARCOS Data is the subject of this motion.

After importing the data, Dr. McCann compared the Processed ARCOS Data to Retail Drug Summary Reports ("RDSR") published by the DEA to confirm the accuracy of his processing. <sup>11</sup> The DEA publishes six ARCOS Retail Drug Summary Reports ("RDSR") each year, which summarize the weight of opioids reported in ARCOS transactions by various combinations of Drug Code, Calendar Quarter, Buyer State, Buyer Zip Code, or Buyer's business activity. Dr. McCann found that the correlation between the RDSRs' reported drug weight and the weights he calculated from the ARCOS Data is 0.999 on a scale from -1.00 to +1.00. This extremely high correlation provides confirmation of the accuracy of his processing of the ARCOS Data he received. <sup>12</sup>

In addition to receiving the ARCOS Data produced by the DEA, Dr. McCann received transactional data produced in discovery by the Defendants,

2042642.1 5

opioids listed in Table 1; (3) transactions where the Action Indicator code, Correction Number, or both suggest the reported transaction is erroneous; (4) transactions involving reverse distributors, analytical labs, importers, exporters, or researchers; (5) transactions reported by the registrant receiving the shipment when two registrants reported the same transaction, keeping the transaction reported by the registrant sending the shipment; (6) transactions with obvious errors in the reported Quantity; and (7) transactions where the Transaction Code is "X" (Lost-in-Transit). Ex. 2 at 25-26. Dr. McCann also corrected the Calculated Base Weight in Grams when it was calculated using an incorrect Ingredient Base Weight from the NDC Dictionary. *Id.* at 26.

<sup>&</sup>lt;sup>11</sup> Ex. 2 at 29.

 $<sup>^{12}</sup>$  *Id*.

AmerisourceBergen Drug, Cardinal Health, and McKesson Corporation.<sup>13</sup> He compared the transactions in each Defendant's data to the ARCOS Data.<sup>14</sup> He then matched the transactions included in the two data sources.<sup>15</sup> Using his matching criteria, over 99.8% of the transactions are included in both the ARCOS Data and all the datasets produced by Defendants.<sup>16</sup> This 99.8% overlap between the ARCOS Data and the datasets produced by Defendants further demonstrates that the ARCOS Data and the datasets produced by Defendants in discovery are both accurate and reliable.<sup>17</sup>

To provide further transparency into his processing technique, Dr. McCann has produced the computer code used for processing and preparing ARCOS data to the Defendants. Indeed, the Defendants have had Dr. McCann's computer code for almost two years. Despite having had significant insight into Dr. McCann's methodology, the defense expert reports have not challenged Dr. McCann's processing, of the data. Rather, several defense expert reports have explicitly acknowledged that they do not dispute the processing, supplementing and

<sup>&</sup>lt;sup>13</sup> *Id*. at 40.

 $<sup>^{14}</sup>$  *Id*.

<sup>&</sup>lt;sup>15</sup> *Id.* at 40.

<sup>&</sup>lt;sup>16</sup> *Id.* at 41.

 $<sup>^{17}</sup>$  *Id*.

<sup>&</sup>lt;sup>18</sup> See Transcript of Frye Hearing, Supreme Court of the State of New York, County of Suffolk, Ex. 4 at 30:22-25-31:2-6.

<sup>&</sup>lt;sup>19</sup> Ex. 3 at 148:11-15.

<sup>&</sup>lt;sup>20</sup> See Ex. 4 at 29:4-20; 57:16-58:21.

summarizing of the ARCOS data and some have actually utilized it in forming their own opinions.<sup>21</sup>

Similarly, there were no disputes raised about the accuracy of Dr. McCann's data during the *Daubert* challenges in the *In Re: National Prescription Opiate Litigation*, Track One Case or during the *Frye* hearings recently held in *In Re Opioid Litigation*, *The County of Suffolk*, *New York v. Purdue Pharma L.P.* pending in Suffolk County, New York.<sup>22</sup>

#### **ARGUMENT**

Because there is no factual dispute that Dr. McCann's Processed ARCOS Data accurately reflects the data provided by the DEA regarding the defendants' shipments of opioids, this Court should grant partial summary judgment on this question.

<sup>&</sup>lt;sup>21</sup> See Expert Report of Robert L. Buskey (Ex. 5 at pp. 39-41, ¶236 (focused review on the methodologies and assumptions underlying the analysis of flagged orders); Expert Report of Peter J. Boberg, PHD (Ex. 6 at p. 5, ¶16)(offered no opinions on the accuracy of Dr. McCann's treatment of the data, and made no corrections or adjustments to his treatment of the data); and Expert Report of Theodore F. Martens (Ex. 7 at p. 2, ¶8)(used the ARCOS data that was "processed, cleansed and corrected by" McCann).

<sup>&</sup>lt;sup>22</sup> See Memorandum of Defendants' Motion to Exclude the Opinions and Testimony of Craig McCann, MDL Doc. 1906-2. at footnote 4 (Plaintiffs also asked McCann to offer certain opinions relating to the reliability of ARCOS and Defendant transactions data, which are not addressed in this motion); see also Transcript of Frye Hearing, Supreme Court of the State of New York, County of Suffolk, (Ex. 4 at 29:4-20; 57:16-58:21).

Rule 56(a), as amended, permits a motion for partial summary judgment with respect to "part of each claim or defense." Rule 56(g) goes further and clarifies that a court "may enter an order stating any material fact--including an item of damages or other relief--that is not genuinely in dispute and treating the fact as established in the case." Because the accuracy of the Processed ARCOS Data is just such a material fact that is not genuinely in dispute, it would be appropriate for this Court to treat it as "established in this case."

The standard for granting a motion for partial summary judgment is wellestablished:

A partial summary judgment "is merely a pretrial adjudication that certain issues shall be deemed established for the trial of the case." Fed.R.Civ.P. 56 advisory committee's note. A motion for partial summary judgment is governed by the same standard applied to consideration of a full motion for summary judgment. See Pettengill v. United States, 867 F.Supp. 380, 381 (E.D.Va.1994) (citing Gill v. Rollins Protective Servs. Co., 773 F.2d 592, 595 (4th Cir.1985)). To obtain summary judgment, the moving party must show that there is no genuine dispute as to any material fact and that the moving party is entitled to judgment as a matter of law. Fed.R.Civ.P. 56(a).

In re Bos. Sci. Corp., Pelvic Repair Sys. Prod. Liab. Litig., No. 2:12-CV-00904, 2015 WL 1527678, at \*1 (S.D. W.Va. Apr. 2, 2015). Similarly, the burden on the party opposing summary judgment is also familiar:

Although the court will view all underlying facts and inferences in the light most favorable to the nonmoving party, the nonmoving party nonetheless must offer some "concrete evidence from which a reasonable juror could return a verdict in his [or her] favor," *Anderson* [v. Liberty Lobby, Inc., 477 U.S. 242, 256 (1986)], that is, more than a mere

<sup>&</sup>lt;sup>23</sup> Rule 56(a) was amended in 2010 to make it clear that motions seeking partial summary judgment were proper with respect to portions of a claim. *See* Advisory Committee Note to the 2010 Amendment to Rule 56.

"scintilla of evidence" in support of his or her position, *id.* at 252. Conclusory allegations or unsupported speculation, without more, are insufficient to preclude the granting of a summary judgment motion. *See Dash v. Mayweather*, 731 F.3d 303, 311 (4th Cir. 2013); *Stone v. Liberty Mut. Ins. Co.*, 105 F.3d 188, 191 (4th Cir. 1997).

In re Bos. Sci. Corp., Pelvic Repair Sys. Prod. Liab. Litig., 2015 WL 1527678, at \*2 (discussing standard for opposing motion for partial summary judgment).

Here, there simply is no dispute regarding the accuracy of the Processed ARCOS Data. Neither the Defendants here (nor elsewhere) have disputed Dr. McCann's processing or the accuracy of the Processed ARCOS Data. Moreover, Defendants and their experts have relied upon it. As a result, the parties and the Court should not waste trial time on proof of this undisputed fact.

### CONCLUSION

The Court should grant partial summary judgment and find that Dr. McCann's Processed ARCOS Data accurately reflects the data provided by the DEA regarding the defendants' shipments of opioids. Because defendants have already stipulated that the DEA data is authentic and may be deemed admissible, the fact that there is no genuine issue of material fact as to the accuracy of Dr. McCann's processing of that data should further result in the conclusion that the Processed ARCOS data should be deemed admissible as well.

Dated: September 22, 2020 Respectfully submitted,

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## CERTIFICATE OF SERVICE

I hereby certify that on September 22, 2020, a copy of the foregoing was filed electronically. Notice of this filing will be sent to all parties by operation of the Court's electronic filing system. Parties may access this filing through the Court's system. This filing will also be served on all parties by email to <a href="mailto:Track2OpioidDefendants@ReedSmith.com">Track2OpioidDefendants@ReedSmith.com</a>, <a href="mailto:MDL2804Discovery@motleyrice.com">MDL2804Discovery@motleyrice.com</a>, and CT2\_Opioid\_Team@mail-list.com.

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2042642.1 11